REMARKS

Claims 28-32, 34, 36, 37 and 53 are pending.

Claim 29 has been amended to more specifically characterize the method, as supported at least at page 4, lines 8-14, and to expressly recite that the growth of said cells is on a biological matrix or a supporting structure and that the growth of said cells is three-dimensional, as supported at least at page 8, last full paragraph.

In addition, claims 28 and 36 have been amended to delete members of a Markush group and claim 34 has been amended so that it does not depend on a canceled claim and to be consistent with the amendments to claim 29.

No new matter is added.

A. Claim Rejections - 35 U.S.C. § 112, second paragraph

In paragraph 4, on page 2 of the Office Action, the Examiner rejects Claims 28-40 under 35 U.S.C. § 112, second paragraph.

In view of the amendments to the Claims, Applicant respectfully submits that the Examiner's rejection has been rendered moot.

B. Claim Rejections - 35 U.S.C. § 102(b)

In paragraph 6, on page 4 of the Office Action, the Examiner maintains the rejection of Claims 28-30 and 32-39 under 35 U.S.C. § 102(b) as being anticipated by Naughton et al.

For the following reasons, Applicant respectfully traverses the Examiner's rejection.

Naughton et al teach a three-dimensional culture system based on a synthetic carrier structure or matrix for prolonged proliferation of desired tissue cells growing within multiple layers of the matrix. The cells of the desired tissue ("tissue-specific cells") are inoculated and cultured on a pre-established 3D stromal matrix. This stromal matrix comprises endogenous fibroblasts which enable the growth of tissue-specific cells in multiple layers on/in said synthetic carrier structure (see the Detailed Description in Naughton et al).

The problem to be solved in Naughton et al is said to be prolonged or maximized proliferation of tissue-specific cells. The solution is the generation of multiple layers of a fibroblast matrix on said synthetic carrier structure, which enables the growth of "tissue-specific cells". Addition of growth factors may assist the growth in the cell system of Naughton et al, but

this was already known. Naughton et al do not teach directly or indirectly that EPO causes in tissue regeneration a separate independent effect not discovered so far, namely, local initiation, termination, structural guidance and three-dimensional growth of tissue. Naughton et al mentions EPO and other growth factors merely accidentally in his tissue culture system which underlies a completely different problem, solution, and approach. Growth factors are used, because they may generally improve growth conditions. Naughton et al do not teach that especially EPO provides a specific effect going beyond the general effect of the other growth factors mentioned simultaneously.

In Naughton et al, EPO is only mentioned merely accidentally, in a listing of potential tissue growth factors, without being exemplified and without giving any teaching that EPO may promote tissue growth.

Thus, the Examiner appears to be basing the rejection on inherent anticipation. As the Examiner knows, in order to maintain a finding of inherent anticipation, the missing descriptive matter must *necessarily* be present in the cited reference. That a certain result or characteristic *may* occur or be present in the cited reference is not sufficient to establish inherency. *In re Rijckaert*, 9F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed.Cir.1993).

Applicant submits that because EPO is not exemplified, the methods disclosed in Naughton et al do not *necessarily* locally initiate, terminate and structurally guide the growth of adult cells such that three-dimensional growth is achieved.

Furthermore, the preamble of Claim 29 has been amended to emphasize that the method achieves local initiation, termination and structural guidance of three-dimensional growth of adult tissue-specific cells on a biological matrix or a supporting structure in an in-vitro tissue regeneration process.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Naughton et al and thus requests withdrawal of the Examiner's rejection.

C. Claim Rejections - 35 U.S.C. § 103

In paragraph 8, on page 6 of the Office Action, the Examiner rejects Claims 28-40 under 35 U.S.C. § 103 as being unpatentable over Naughton et al in view of Chen et al.

Specifically, the Examiner states that although Naughton et al do not teach all of the growth factors recited in the present claims, such growth factors were well-known and used in the art to generate cells into tissues as evidenced by Chen et al, which teaches culturing endothelial cells in the presence of VEGF.

For the following reasons, the rejection is overcome.

As discussed above, Naughton et al do not teach or suggest the present invention, in particular the use of "adult tissue-specific" cells, and Chen et al does not provide the deficiencies which exist therein.

Furthermore, the present invention is based on the unexpected finding that EPO, which was known to promote the growth of hematopoietic cells, especially red blood cells, can also trigger the growth of "adult tissue-specific" cells, and can be therefore directly used for tissue regeneration, for example, during wound healing processes. Applicant found that EPO unexpectedly is able to promote structurally guided 3D growth of said tissue cells.

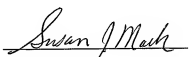
Claim 29 has been amended also to recite this unexpected feature of the present invention.

Accordingly, Applicant respectfully submits that the present invention is not taught or suggested in Naughton et al alone or in view of Chen et al, and thus requests withdrawal of the Examiner's rejection.

In view of the amendments to the claim and the arguments set forth above, reexamination, reconsideration and allowance are respectfully requested.

The Examiner is invited to contact the undersigned at his Washington telephone number on any questions which might arise.

Respectfully submitted,



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Date: June 21, 2008